

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KH/SG/BR045765	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/FR2004/000775	International filing date (day/month/year) 26.03.2004	Priority date (day/month/year) 28.03.2003

International Patent Classification (IPC) or national classification and IPC

Applicant

VEDALAB

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. (*sent to the applicant and to the International Bureau*) a total of 4 sheets, as follows:
 - sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- international search (Rule 12.3 and 23.1(b))
 publication of the international application (Rule 12.4)
 international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- the international application as originally filed/furnished
 the description:
 pages 1-20 as originally filed/furnished
 pages* _____ received by this Authority on _____
 pages* _____ received by this Authority on _____
- the claims:
 nos. _____ as originally filed/furnished
 nos.* _____ as amended (together with any statement) under Article 19 28.01.05 with the letter of 28.01.05
 nos.* 1-13 received by this Authority on _____
 nos.* _____ received by this Authority on _____
- the drawings:
 sheets 1/5-5/5 as originally filed/furnished
 sheets* _____ received by this Authority on _____
 sheets* _____ received by this Authority on _____
- a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. The amendments have resulted in the cancellation of:
- the description, pages _____
 the claims, nos. _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to sequence listing (*specify*): _____
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- the description, pages _____
 the claims, nos. _____
 the drawings, sheets/figs _____
 the sequence listing (*specify*): _____
 any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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International application No.
PCT/FR2004/000775

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-13	YES
	Claims		NO
Inventive step (IS)	Claims	1-13	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)**1.** Reference is made to the following documents:

D1: EP-A-0 458 231;
D2: EP-A-0 462 376.

2. The subject matter of claims 1-13 is considered to be novel and inventive under the terms of PCT Article 33(2) and 33(3), for the following reasons:

Document D1 (see column 4, line 26 to column 6, line 20), which is considered to be the prior art closest to the subject matter of claim 1, describes a method for detecting an analyte using a solid substrate that includes a capture reagent immobilised in the detection area. The liquid sample and the conjugated binding reagent are deposited separately, sequentially and extemporaneously on the collection area (in a dipstick, the collection area is also the detection area).

D2 describes a similar immuno-chromatographic

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Box No. V	<u>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</u>
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method for detecting an analyte, wherein the liquid sample and the conjugated binding reagent are optionally deposited separately and sequentially on the substrate (said document does not indicate the preferred order of deposition).

The method as per independent claim 1 differs from the one described in D1 in that the conjugated binding reagent is deposited on the collection area before the sample. The immediate, full contact between the sample and the marked binding reagent reduces background noise and the hook effect by increasing method sensitivity.

Even though D2 describes the option of pre-depositing the binding reagent on the substrate before adding the liquid sample, the binding reagent is not deposited "extemporaneously and in liquid form" before said liquid sample (column 5, lines 34-37; page 8, lines 24-27).

It follows that a person skilled in the art, having access to documents D1 and D2, would not have reversed the order of deposition of the reagents in the method described in D1 in order to reduce the hook effect and would not have developed a method in which the binding reagent is deposited before the liquid sample (or before the liquid diluent), such as the method in independent claims 1 and 3-4 (D1, column 4, lines 10-11, describes a method in which the diluent is deposited before the conjugated binding reagent

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and D2 does not describe the option of using a diluent).